

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

IN RE: BOSTON SCIENTIFIC CORP.  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION

MDL No. 2326

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THIS DOCUMENT RELATES TO THE CASES ON THE ATTACHED EXHIBIT A

**MEMORANDUM OPINION AND ORDER**  
**(*Daubert* Motion re: Dr. Stephen F. Badylak, D.V.M., Ph.D., M.D.)**

Pending in *In re Boston Scientific Corp.*, No. 2:12-md-2326, MDL 2326, is the Plaintiffs' Motion to Exclude the Opinions and Testimony of Stephen F. Badylak, D.V.M., Ph.D., M.D. [ECF No. 5826]. The Motion is now ripe for consideration because the briefing is complete. As set forth below, the plaintiffs' Motion is **DENIED**.

**I. Background**

This group of cases resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation ("MDL") concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the six remaining MDLs, there are more than 17,000 cases currently pending, approximately 3800 of which are in the Boston Scientific Corp. ("BSC") MDL, MDL No. 2326.

In an effort to manage the massive BSC MDL efficiently and effectively, I decided to conduct pretrial discovery and motions practice on an individualized basis. To this end, I selected certain cases to become part of a "wave" of cases to be prepared for trial and, if necessary, remanded.

Upon the creation of a wave, I enter a docket control order subjecting each active case in the wave to the same scheduling deadlines, rules regarding motion practice, and limitations on discovery. *See, e.g.*, Pretrial Order (“PTO”) # 165, *In re Bos. Sci. Corp. Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-md-02326, June 21, 2017, <http://www.wvsc.uscourts.gov/MDL/boston/orders.html>. Included among the discovery rules imposed by the court is the obligation of the parties to file *Daubert* motions seeking to limit or exclude the testimony of general causation experts in the main MDL, MDL 2326.

## II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if it will “help the trier of fact to understand the evidence or to determine a fact in issue” and (1) is “based upon sufficient facts or data” and (2) is “the product of reliable principles and methods,” which (3) has been reliably applied “to the facts of the case.” Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it “rests on a reliable foundation and is relevant.” *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to “prove” anything. However, he or she must “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court’s role as gatekeeper is an important one. “[E]xpert witnesses have the potential to be both powerful and quite misleading”; the court must “ensure that any and all scientific testimony . . . is not only relevant, but reliable.” *Cooper v.*

*Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Daubert*, 509 U.S. at 588, 595; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999)). I “need not determine that the proffered expert testimony is irrefutable or certainly correct. As with all other admissible evidence, expert testimony is subject to testing by ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (alteration in original) (citation omitted) (quoting *Daubert*, 509 U.S. at 596); see also *Md. Cas. Co.*, 137 F.3d at 783 (“All *Daubert* demands is that the trial judge make a ‘preliminary assessment’ of whether the proffered testimony is both reliable . . . and helpful.”).

*Daubert* mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory “can be (and has been) tested”; (2) whether the theory “has been subjected to peer review and publication”; (3) the “known or potential rate of error”; (4) the “existence and maintenance of standards controlling the technique’s operation”; and (5) whether the technique has achieved “general acceptance” in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, “[t]he inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); see also *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) (“We

agree with the Solicitor General that “[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert’s particular expertise, and the subject of his testimony.” (alteration in original)); *see also Crisp*, 324 F.3d at 266 (noting “that testing of reliability should be flexible and that *Daubert*’s five factors neither necessarily nor exclusively apply to every expert”).

With respect to relevancy, *Daubert* also explains:

Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of “fit.” “Fit” is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702’s “helpfulness” standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

*Daubert*, 509 U.S. at 591-92 (citations and internal quotation marks omitted).

### III. Analysis

Dr. Badylak is the Deputy Director of the McGowan Institute for Regenerative Medicine, Director of the Center for Preclinical Studies, and a tenured professor with the Department of Surgery at the University of Pittsburgh.

#### A. Material Safety Data Sheets (“MSDS”)

First, plaintiffs seek to exclude Dr. Badylak’s opinions related to MSDSs created by Chevron Phillips for polypropylene on the basis that his opinions constitute improper state of mind or intent testimony. Specifically, Dr. Badylak intends to offer the opinion that the Medical Application Caution contained on the MSDS was not supported by any scientific data. The Medical Application Caution

states, “Do not use this Chevron Phillips Chemical Company LP material in medical applications involving permanent implantation in the human body or permanent contact with internal body fluids or tissues.” I agree with BSC that Dr. Badylak’s opinion regarding the scientific support for this warning is not improper “state of mind” testimony. Therefore, the plaintiffs’ Motion on this point is **DENIED**.

### **B. Risk-Benefit Analysis or Safety and Efficacy**

Second, plaintiffs contend that Dr. Badylak should be precluded from opining on the safety and efficacy of polypropylene mesh devices because he has not reviewed the applicable scientific literature and he has no clinical experience using these devices. Dr. Badylak’s expert report indicates that he reviewed more than two hundred relevant scientific publications, including more than twenty publications evaluating the safety and efficacy of BSC devices. Furthermore, Dr. Badylak explains that he is more familiar with the body of literature reviewing the safety and efficacy of surgical mesh generally, versus literature specific to any one device. This explanation does not undermine his qualifications but instead clarifies his approach. If there are certain device-specific publications that Dr. Badylak failed to review in preparing his expert report, plaintiffs are free to ask him about those publications on cross-examination.

Similarly, the plaintiffs’ arguments regarding Dr. Badylak’s clinical experience are also without merit. Dr. Badylak has extensive experience in the field of biomaterials, including the design of implantable surgical mesh devices. Accordingly,

the plaintiffs' Motion with regard to Dr. Badylak's safety and efficacy opinions is **DENIED**.

**C. Lack of Correlation Between Microscopic Findings of Explanted Mesh and Clinical Symptoms**

Third, plaintiffs seek to exclude Dr. Badylak's opinion that microscopic findings of explanted polypropylene mesh "does not correlate to any clinical finding of pain or other purported adverse event." Plaintiffs contend that BSC never disclosed that Dr. Badylak would offer this opinion. However, BSC points out that this opinion appears in a number of Dr. Badylak's *case-specific* supplemental reports. As this opinion is case-specific, arguments on whether to exclude the opinion are better suited for case-specific *Daubert* motions, filed in the individual cases in which the opinion will be offered. Accordingly, the plaintiffs' Motion on this point is **DENIED**.

**D. Degradation**

Finally, plaintiffs seek to exclude Dr. Badylak's opinions regarding oxidative degradation because he 1) failed to investigate an alternative theory of degradation proposed by Dr. Iakovlev (plaintiffs' expert), and 2) contradicted himself during his deposition by acknowledging the "phenomenon" of oxidative reactions. First, Dr. Badylak explained during his deposition that he did consider a number of alternative theories of degradation. His failure to fully investigate the particular theory proposed by the plaintiffs' expert does not render his opinions unreliable. If plaintiffs believe that Dr. Badylak did not give sufficient consideration to the alternative theory proposed by Dr. Iakovlev, they can address this purported deficiency on cross-examination.

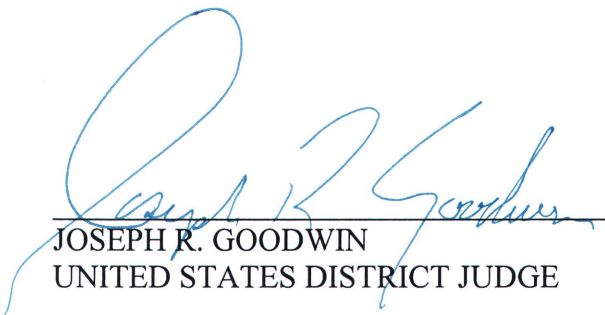
Second, after acknowledging the “phenomenon” of oxidative reactions, Dr. Badylak stated that he does not believe that oxidative reactions at the surface of polypropylene result in the degradation that causes further problems. Upon review of the deposition, I do not find Dr. Badylak’s testimony sufficiently contradictory to undermine the reliability of his expert opinions. Accordingly, the plaintiffs’ Motion with regard to degradation is **DENIED**.

#### **IV. Conclusion**

To summarize, the plaintiffs’ *Daubert* Motion concerning Dr. Badylak [ECF No. 4826] is **DENIED**.

The court **DIRECTS** the Clerk to file a copy of this Memorandum Opinion and Order in 2:12-md-2326 and all individual cases listed on the attached Exhibit A. The court further **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: May 29, 2018



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JOSEPH R. GOODWIN  
UNITED STATES DISTRICT JUDGE

## EXHIBIT A

Case Number	Case Name
2:17-cv-02588	Adams v. Boston Scientific Corporation
2:17-cv-01837	Allen v. Boston Scientific Corporation
2:17-cv-02443	Allex v. Boston Scientific Corporation
2:17-cv-02243	Alvarado v. Boston Scientific Corporation
2:17-cv-02202	Atwood v. Boston Scientific Corporation
2:17-cv-00701	Babcock v. Boston Scientific Corporation
2:17-cv-02589	Barnett v. Boston Scientific Corporation
2:17-cv-01996	Benson v. Boston Scientific Corporation
2:17-cv-02730	Black v. Boston Scientific Corporation
2:17-cv-02446	Blalock v. Boston Scientific Corporation
2:17-cv-01243	Brown v. Boston Scientific Corporation
2:17-cv-02111	Busby v. Boston Scientific Corporation
2:17-cv-02638	Buttke v. Boston Scientific Corporation
2:17-cv-02447	Casale v. Boston Scientific Corporation
2:17-cv-02590	Childress v. Boston Scientific Corporation
2:17-cv-02110	Clark v. Boston Scientific Corporation
2:17-cv-02448	Clark v. Boston Scientific Corporation



2:17-cv-02449	Cole v. Boston Scientific Corporation
2:17-cv-01940	Conley v. Boston Scientific Corporation
2:17-cv-02505	Cutlip v. Boston Scientific Corporation
2:17-cv-02486	Daniell v. Boston Scientific Corporation
2:17-cv-01074	Dembski v. Boston Scientific Corporation
2:17-cv-02592	Dickeson v. Boston Scientific Corporation
2:17-cv-01979	Dunford et al v. Boston Scientific Corporation
2:17-cv-01242	Evans v. Boston Scientific Corporation
2:17-cv-01862	Faso et al v. Boston Scientific Corporation
2:17-cv-02646	Gottfreid v. Boston Scientific Corporation
2:17-cv-00294	Grigg v. Boston Scientific Corporation
2:17-cv-01977	Hardwick v. Boston Scientific Corporation
2:17-cv-02641	Harrison-Hood v. Boston Scientific Corporation
2:17-cv-01900	Hauff et al v. Boston Scientific Corporation
2:17-cv-02734	Henjum v. Boston Scientific Corporation
2:17-cv-02508	Jeter v. Boston Scientific Corporation
2:17-cv-00047	Long v. Boston Scientific Corporation
2:17-cv-01959	Lowrie v. Boston Scientific Corporation

2:17-cv-00568	Mahnke v. Boston Scientific Corporation
2:17-cv-02459	Mallory v. Boston Scientific Corporation
2:17-cv-02461	Martin v. Boston Scientific Corporation
2:17-cv-02738	Martin v. Boston Scientific Corporation
2:17-cv-02739	Martinez v. Boston Scientific Corporation
2:17-cv-02417	Masterson v. Boston Scientific Corporation
2:17-cv-02596	McFolling v. Boston Scientific Corporation
2:17-cv-02462	McSween v. Boston Scientific Corporation
2:17-cv-02467	Melrose v. Boston Scientific Corporation
2:17-cv-02742	Morales v. Boston Scientific Corporation
2:17-cv-02597	Morgan v. Boston Scientific Corporation
2:17-cv-00534	Notestine v. Boston Scientific Corporation
2:17-cv-02416	Palmer v. Boston Scientific Corporation
2:17-cv-02093	Pamensky Murray v. Boston Scientific Corporation
2:17-cv-02633	Pierson et al v. Boston Scientific Corporation
2:17-cv-02470	Porter v. Boston Scientific Corporation
2:17-cv-02477	Pouncy v. Boston Scientific Corporation
2:17-cv-01939	Price v. Boston Scientific Corporation

2:17-cv-02598	Reid v. Boston Scientific Corporation
2:17-cv-02599	Reyes v. Boston Scientific Corporation
2:17-cv-02600	Rinaldi v. Boston Scientific Corporation
2:17-cv-02107	Ross v. Boston Scientific Corporation
2:17-cv-01938	Schroder v. Boston Scientific Corporation
2:17-cv-02745	Shaw v. Boston Scientific Corporation
2:17-cv-02481	Shepard v. Boston Scientific Corporation
2:17-cv-01845	Shiflet v. Boston Scientific Corporation
2:17-cv-02483	Smith v. Boston Scientific Corporation
2:17-cv-02551	Solomon v. Boston Scientific Corporation
2:17-cv-02244	Speed v. Boston Scientific Corporation
2:17-cv-02553	Spencer v. Boston Scientific Corporation
2:17-cv-02787	Stapf v. Boston Scientific Corporation
2:17-cv-00528	Sustaita v. Boston Scientific Corporation
2:17-cv-00536	Sutiff v. Boston Scientific Corporation
2:17-cv-01241	Tigner v. Boston Scientific Corporation
2:17-cv-02450	Wallace v. Boston Scientific Corporation
2:17-cv-02568	Welsh v. Boston Scientific Corporation

2:17-cv-02106	Wilson v. Boston Scientific Corporation
2:17-cv-02571	Wittenborn v. Boston Scientific Corporation
2:17-cv-01098	Zeiter v. Boston Scientific Corporation